

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCE

AFA

In Re Application of: Frank Forrest Humbles

Serial No.:

10/698,205

Examiner: Mayo, Tara L.

Art Unit: 3671

Filing Date:

31 October 2003

Appeal #:

Invention:

SURGICAL ARM POSITIONING PAD

May 3, 2006

Board of Patent Appeals and Interference United States Patent and Trademark Office Post Office Box 1450 Alexandria, Virginia 22313-1450

Dear Sir:

Enclosed is an Appeal Brief to be filed in the above patent application. The Applicant has not been provided with any Filing Receipt for the Notice of Appeal, which was filed with a Certificate of Service on March 7, 2006 and with a date stamp of March 10, 2006. Enclosed with the Brief is a check for \$250.00, the fee for filing a Brief in an Appeal for a small entity. Here, the Applicant, Frank Forrest Humbles, qualifies as a small entity. Also enclosed is a Return Receipt postcard, which should be date stamped and returned to me. If anything further is required from me, please advise me immediately. Thank you very much for your help in this matter.

This the  $\frac{\mathcal{S}}{}$  day of  $\frac{\mathcal{M}_{CQ}}{}$ , 2006.

Michael E. Mauney Attorney at Law Post Office Box 10266 Southport, NC 28461 Telephone (910) 457-0056 Registration #33731



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## BRIEF OF THE APPELLANT

This is an Appeal from a final rejection dated 8 December 2005 rejecting claims 1 through 12. This brief is accompanied by the requisite fee as set forth in section 1.117(f).

#### REAL PARTY IN INTEREST

The real party in interest is the applicant, Frank Forrest Humbles.

#### RELATED APPEALS AND INTERFERENCE

There are no related appeals or interference that would directly affect or be affected by the Board's decision in this pending appeal.

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#### **STATUS OF CLAIMS**

This application was filed on October 31, 2003. There were 12 claims in the application, including two independent claims (Claims 1 and 7). In the Examiner's first Office Action, Claim 1 was objected to because the Examiner felt that the term "positional" should have been "positionable." Claims 7-11 were rejected under 35 U.S.C. 102(b) as being anticipated by Vinci, U. S. Patent #5,549,121. Claims 1-6 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vinci, U. S. Patent #5,549,121 in view of Tari, U. S. Patent #4,662366.

Applicant responded on September 29, 2004. Applicant amended Claim 1 to overcome the objection to the term "positional" as well as to add clarifying language to Claims 1, 2, 3, 4, 5, 7, 8, and 12. On October 21, 2004, the Examiner responded in a final Office Action rejecting all claims. Claims 7-12 were rejected under 35 U.S.C. 102(b) as being anticipated by Witter, U. S. Patent #3,884,225, new prior art. Claims 1-6 were rejected under 35 U.S.C. 103(a) as unpatentable over Vinci, U. S. Patent #5,549,121 in view of Witter, '225 and Tari, U. S. Patent #4,662,336.

On February 9, 2005, Applicant was advised by the Examiner that if Applicant canceled Claims 7-12 and made amendments to Claims 1-6 in accordance with the Examiner's suggestion in that phone call, then Claims 1-6 would be found allowable by the Examiner. Conditional on the understanding that Applicant's amendments would result in a Notice of Allowance, Applicant requested amendments be entered by the Examiner to Claims 1-6 and canceling Claims 7-12. Applicant was later advised by the Examiner in another phone call that the Examiner did not have the authority to enter the Applicant's proposed conditional amendments, that the Applicant would be required to file a a Request for Continued Examination, and that the final rejections remained as final.

Following this final rejection, Applicant filed a Request for Continued Examination.

Applicant amended Claims 1, 3, 5, 7, 8, 9, 10, 11, and 12 and responded with arguments to the Examiner's final rejection. In an Office Action dated July 25, 2005, responding to the Request for

Continued Examination, the Examiner again rejected Claims 1-12. Here, the Examiner, for the first time, rejected Claims 2-6 and 10-12 under 35 U.S.C. 112 for the use of the term "easily" and the term "quickly." These terms were present in the claims in the original application and had gone through prior Office Actions from the Examiner without the Examiner previously rejecting Claims 2-6 and 10-12 on the grounds that these terms made the claims indefinite. Claims 1-6 were rejected under 35 U.S.C. 103(a) as unpatentable over Ogburn, U. S. Patent #2,245,293 in view of Witter, ',225 and Tari, '336. Claims 7-11 were rejected under Ogburn '293 in view of Witter '225 under 35 U.S.C. 103(a). Claim 12 was rejected under Ogburn '293 in view of Witter '225 and Tari '336 under 35 U.S.C. 103(a).

Applicant responded to this Office Action on September 26, 2005, advancing arguments why the terms both "easily" and "quickly" did not render the claims indefinite and that the Examiner was incorrect to reject the claims under 35 U.S.C. 112. Applicant also responded to claims rejections under 35 U.S.C. 103.

In the 8 December 2005 final Office Action, the Examiner maintained the rejections under 35 U.S.C. 112 objecting to the terms "easily" and "quickly." The Examiner maintained the rejections under 35 U.S.C. 103 using the same combinations of prior art as had been previously raised by the Examiner. It is from this final Office Action that this Appeal is made.

The current status of the claims as set out in the Examiner's last Office Action with a mailing date of December 8, 2005 is as follows:

Claims objected to - none.

Claims allowed - none.

Claims finally rejected - Claims 2-6 and 10-12 were rejected under 35 U.S.C. 112.

- Claims 1-12 were rejected under 35 U.S.C. 103(a).

Claims appealed - The Applicant is appealing the final rejections of Claims 1-12.

# STATUS OF THE AMENDMENTS

All amendments offered by the Applicant have been entered by the Examiner and there are no pending amendments. Claims set out in the Appendix include all entered amendments.

#### SUMMARY OF THE CLAIMED SUBJECT MATTER

Claims 1 and 7 are independent claims. The explanation of the subject matter defined for each independent claim will be given first. After each independent claim, dependent claims will be summarized. The specification will be referred to by page and line number. The drawings will be referred to by figure number and reference characters. For clarity in the specification, headings and titles will not be counted in determining line numbers

#### Claim 1

Claim 1 is an independent claim. Claim 1 has five elements defined in subparagraphs (a) - (e). Claim 1 defines an arm protection apparatus for positioning a patient's arms when in a prone or supine position on a patient support comprising:

"(a) at least one soft cushion pad with a central portion positionable under the patient's body;"

The soft cushion pad (10) is seen in Figures 2 and 3. The central portion is demonstrated in Figure 3 as the portion which is underneath the patient (400) who is shown in dotted lines in Figure 3.

"(b) on said at least one soft cushion pad, a soft cushion pad right arm upper section positionable around an upper right arm of a patient including means for attaching said soft cushion pad right arm upper section to said central portion of said at least one soft cushion pad so that said soft cushion pad right arm upper section is folded around a patient's upper right arm;"

The right arm of upper section (21) is seen in Figure 2. It folds around a patient's right arm seen in Figure 3 and attaches by means of the attachment tape (61 and 65). The attachment tape (61 and 65) are the means for attaching required in section (b).

"(c) on said at least one soft cushion pad, a left soft cushion pad arm upper section positionable around an upper left arm of a patient including means for attaching said left arm soft cushion pad upper section to said central portion of said at least one soft cushion pad so that said soft cushion pad left arm upper section is folded around a patient's upper left arm;"

The left arm upper section (12) of the soft cushion pad (10) is seen in Figure 2 and is shown in Figure 3 folded around a patient's upper left arm. Again, the means for attaching is shown by the attaching tape (60 and 64).

"(d) on said at least one soft cushion pad, a right soft cushion pad arm lower section positionable around a lower right arm of a patient including means for attaching said soft cushion pad right arm lower section to said central portion of said at least one soft cushion pad so that said soft cushion pad right arm lower section is folded around a patient's lower right arm;"

The lower right arm section (31) of the soft cushion pad (10) is shown flat and extended in Figure 2. Figure 3 shows the right arm section (31) of the soft cushion pad (10) folded around a patient's (400) lower right arm and attached by means of the attachment tape (71 and 75) as shown in Figures 2 and 3.

"(e) on said at least one soft cushion pad, a soft cushion pad left arm lower section positionable around a lower left arm of a patient including means for attaching said soft cushion pad left arm lower section to said central portion of said at least one soft cushion pad so that said soft cushion pad left arm lower section is folded around a patient's lower left arm."

The lower left arm section (30) of the soft cushion pad (10) is shown unfolded and extended in Figure 2 with the attachment tape(70 and 74) shown in Figure 2. It is shown positioned around a patient's lower left arm in Figure 3 with the lower left arm section (30) folded around a patient's (400) lower left arm and attached by means of the attachment tape (70 and 74).

It can be seen in Figures 2 and 3 the soft cushion pad is positionable underneath a patient's body (400). The arm sections (20, 21; 30, 31) fold around a patient's left and right arms generally enclosing the arm from approximately the arm pit to the elbow for the upper sections (20,

21) and from the elbow to the wrist for the lower sections (30, 31). The arm protector pad is made of a soft yielding foam-like material (page 8, lines 23-24). This provides a cushioning effect for a patient's arm while also positioning a patient's arm in a manner that may avoid a stretching injury to nerves within the arm (page 8, line 24 - page 9, line 2).

Claim 2 is a claim that is dependent on Claim 1. Consequently, it has the five elements as defined in Claim 1, but has the additional requirement that the "soft cushion pad is made of material that is easily cut whereby a portion of the soft cushion pad may be cut away when necessary for visualizing a portion of the patient's body that may otherwise be covered by said at least one soft cushion pad." The importance of the additional limitation of material that is easily cut is explained on page 9. First, it is described that the arm sections of the soft cushion pad may be quickly and easily detached from the central sections (page 9, lines 4-7). The foam material of which the pad is constructed is defined as made so that it can be "cut away with standard cutting tools available in a standard operating room such as scissors." (Application page 9, lines 8-9). It is also described that the pad could be constructed with pre-perforated tear-a-way sections of the foam material to facilitate removal of a portion of the arm protector pad if necessary to gain access to a vein or artery of the patient. (Application page 9, lines 9-12).

Claim 3 depends on Claim 2 and adds a provision that the means for attaching of the left and right arm upper sections and left and right arm lower sections are such that the sections may be "easily and quickly attached and detached from said central portion of said at least one soft cushion pad." A preferred embodiment is described as using "Velcro<sup>TM</sup>-like attachment materials." "Velcro<sup>TM</sup>-like attachment materials" are simply a miniature hook-and-eye arrangement. However, other equivalent means of attachment such as tapes with sticky material or the like, could also be used.

Claim 4 is dependent on Claim 3 and adds the requirement that "said at least one soft cushion pad is radiolucent." This requirement is described on page 9, lines 12-13. It is useful that the cushion pad (10) be radiolucent, so that it need not be removed or otherwise repositioned for x-rays.

Claim 5 is a dependent claim and depends on Claim 4. It adds the requirement that the soft cushion pad is "comprised of a first rectangular section, a second rectangular section, with said first and second rectangular sections connected thereby forming a generally H shape with said soft cushion pad right arm upper section, soft cushion pad left arm upper section, soft cushion pad right arm lower section, and soft cushion pad left arm lower section comprising legs of said general H shape." This is seen clearly in **Figure 2** of the preferred embodiment. There the first rectangular section is (12) and the second rectangular section is (14) and they are connected by the central portion of the soft cushion pad (10) positionable under a patient's (400) body forming a generally H shape as seen in **Figure 2**.

Claim 6 depends on Claim 5 and adds the requirement that "said generally H shape has a width approximately equal to the length of a patient's torso." This definition of the width of the cushion pad (10) of the generally H shape as seen in **Figure 3**, which extends generally from underneath a patient's (400) arm at approximately the arm pit level all the way down a patient's (400) body to approximately the wrist.

Claim 7 is an independent claim with three elements defined in subparagraphs (a), (b), and (c). Subparagraph (a) calls for:

"(a) at least one central cushion pad, said central cushion pad sized to be positioned under the torso of a patient;"

The cushion pad (10) is shown in Figure 2 generally and shown in Figure 3 positioned under a patient (400) shown in dotted lines.

"(b) attached on said central cushion pad, at least one arm section cushion pad with an arm end extending away from said central cushion pad, said at least one arm section cushion pad sized to loop around at least a portion of an arm of a patient;"

Again, the cushion pad (10) is shown in Figures 2 and 3. Any of the arm sections (20, 21, 30, 31) define an arm section cushion pad which extends away from said central cushion pad and sized to loop around at least a portion of the arm of a patient (400) as is shown in Figure 3.

"(c) means for attaching said arm end of said at least one arm section cushion pad to said

central cushion pad whereby at least a portion of an arm of a patient may be contained within said at least one arm section cushion pad looped around an arm of a patient and held into place in proximity to a patient's torso."

The means for attaching are the attachment tapes (61, 65; 64, 60; 71, 75; 70, 74)

These means for attachment are described as "attachment tapes" and, in the preferred embodiment, constructed of a "Velcro™-like" material

Claim 8 is dependent on Claim 7, which further limits the elements of Claim 7 to require "a plurality of said arm section cushion pads." This, of course, means there are at least two arm cushion pads shown as the arm sections (12) and (14).

Claim 9 is dependent on Claim 8 and adds the requirement that the arm section cushion pads are radiolucent. The desirability of radiolucent construction is described on page 9, lines 12-13 because it obviates the need that the device be removed or repositioned for x-rays.

Claim 10 depends on Claim 9 and adds the limitation that "said means for attaching readily attach and detach." This is generally the desirability of having something readily and quickly removed and is generally described in the application on page 9. It suggests that the attachment means should be "Velcro<sup>TM</sup>-like" material.

Claim 11 depends on Claim 10 and adds the requirements that the arm section cushion pads "are constructed of material that is easily cut away." The importance of this additional limitation is explained on page 9. The arm section pads should be quickly and easily detached from the central section (page 9, lines 4-7). The foam material of which the device is constructed is defined as being made so that it can be "cut away with standard cutting tools available in a standard operating room such as scissors." (Application page 9, lines 8-9). It is also described as pre perforated tear-a-way foam material. (Application page 9, lines 9-12).

Claim 12 depends on Claim 11 and adds the requirement that there be "four arm section cushion pads attached to said central cushion pad, each arm section cushion pads sized to fit around

approximately one-half of a patient's arm." This is shown generally in Figures 2 and 3, where the arm sections (30, 31; 20, 21) are folded generally around a portion of a patient's (400) arms.

#### **GROUNDS FOR REJECTION TO BE REVIEWED ON APPEAL**

Claims 1-6 were rejected under 35 U.S.C. 103(a) as unpatentable over Ogburn, U. S. Patent #2,245,293, in view of Witter, U. S. Patent #3,884,225, and under Tari, U. S. Patent #4,662,336.

Claims 7-11 were rejected under the combination of Ogburn, U. S. Patent #2,245,293 in view of Witter, U. S. Patent #3,884,225. Claim 12 was rejected under the combination of Ogburn, U. S. Patent #2,245,293, in view of Witter, U. S. Patent #3,884,225, and Tari, U. S. Patent #4,662,336.

Claims 2-6 and Claims 10-12 were rejected under 35 U.S.C. 112 because of terms that rendered the claims indefinite. Claim 2 was rejected to because of the term "easily" is a relative term which renders a claim indefinite. Claim 3 which depends on Claim 2 was rejected for the recitation of "easily" and "quickly." The remaining claims 4-6 are dependent on Claims 2 and 3, hence are be rejected because of the terms "easily" and "quickly" incorporated in those terms because of their dependence on Claims 2 and 3.

Claim 10 was rejected for the recitation of the term "quickly." Claims 11 and 12 depend on Claim 10 and incorporate the objected to term "quickly" because of the dependence on the underlying Claim 10 and were also rejected.

#### <u>ARGUMENT</u>

#### 103(a) Rejections

The Examiner uses the combination of Ogburn '293, Witter '225, and Tari '336 to reject Claims 1-6 under 35 U.S.C. 103(a). For Claim 1, the Examiner reasoned that Ogburn shows a "arm protection apparatus (2)" and the Ogburn arm protection apparatus is used for "positioning a patient's arms (11)." The Examiner further reasons regarding Claim 1 that Ogburn discloses:

"(a) at least one member with a central portion (11) positionable under a patient's body;

- (b) on said one member a soft cushion pad right arm section (19) positionable on the right arm of a patient including means for attaching (33, 34, and 35, collectively), said soft cushion pad right arm section to said central portion of said at least one member so that said soft cushion pad right arm section is foldable around a patient's right arm; and
- (c) on said at least one member a soft cushion pad left arm section (19) positionable around the left arm of a patient including means for attaching (33, 34, and 35, collectively), said soft cushion pad left arm section to said central portion of said at least one member so that said soft cushion pad left arm section is folded around a patient's arm."

Consider this reasoning of the Examiner.

First, the Ogburn disclosure describes the device and titles the patent as "Restraining Device." It is specifically designed to restrain the movement of arms or legs of a patient who might inflict injury upon themselves or others or interfere with the surgeon who is performing an operation. (Ogburn, Column 1, lines 1-7). Because it is designed for insane or delirious patients, the device must necessarily be constructed so as to provide a secure restraint for the arms of a patient. This means that a wide strap (11), preferably a leather or similar material, is adopted to be secured in place on top of the bed by a securing strap (13), which passes under the bed and buckles into place. (Ogburn, Column 2, lines 39-46). Attached to this base member and slidably mounted are "cuff members" (16 and 17). Each cuff member comprises a rectangular piece (16) of relatively heavy stiff leather or similar material upon which a padding (19) is attached by stitching. Straps (21) may be buckled to hold the cuff connected to the arm or the leg of the patient. (Ogburn, Column 2, lines 54 to Column 3, line 16).

The Applicant traverses the conclusion of the Examiner that Ogburn shows a "arm protection apparatus" Neither the term "arm protection apparatus" nor the reference number (2), are found anywhere in the Ogburn '293 reference. Apparently, the Examiner was unable to actually find a reference in the Ogburn patent to the use of the Ogburn cuffs for protection of the arms of a patient, decided to remedy this deficiency by fabricating an "arm protection apparatus"

(2)." Obviously, if an Examiner can fabricate terms and reference numbers for prior art, it will be difficult for any applicant to overcome a prior art reference used by an examiner since the examiner may, at will, remedy any deficiencies in that prior art by making up whatever is needed. Ogburn does disclose a strap (11) which maybe positioned under or over a patient's body. The Examiner goes on to reason that there is a "soft cushion pad right arm section (19)." The padding (19) disclosed in Ogburn is underneath hard leather cuffs (16, 17). Consequently, the Applicant traverses the conclusion of the Examiner that the padding (19) of Ogburn, which is found stitched under a hard leather cuff (16 and 17) constitutes a "soft cushion pad right arm section." The Examiner likewise takes the padding (19) of Ogburn to assert that it is a "soft cushion pad left arm section (19)." Applicant traverses this conclusion of the Examiner. The Ogburn cuff members (16) and 17) are "preferably a rectangular piece of heavy relatively stiff leather." (Ogburn, Column 2, lines 1-3). Consequently, the Examiner takes the two heavy stiff leather cuffs (16 and 17) of Ogburn and turns them into a soft cushion pad right arm and left arm section by referencing the padding (19), which is mounted underneath the cuffs, apparently the prevent injury to patients from those cuffs. Applicant traverses these conclusions of the Examiner regarding the teaching of Ogburn.

For Claim 2, the Examiner reasons that "said member is made of material that is easily cut." First, nothing in Applicant's Claim 1 refers to a "member" nor is that reference found in the Ogburn patent. Therefore, it is unclear what the Examiner means by the language "said member." Having confused the issue by using terms that are present neither in the Applicant's disclosure or claims or in the Ogburn reference, the Examiner goes on the state that this member "is made of material that is easily cut whereby a portion of the member may be cut away when necessary for visualizing a portion of the patient's body that may be otherwise covered by said at least one member." First, Ogburn discloses hard leather cuffs (16 and 17). The purpose of these cuffs is to secure an insane or delirious patient's arms or legs. Consequently, to make these cuffs of material that is easily cut away, is to defeat their primary purpose of securing the arms and legs of an insane or delirious patient. The only reason the Examiner would ever transform the hard leather cuffs (16 and 17) of the Ogburn reference into material that may be easily cut, is because of the teaching of the Applicant's invention of the desirability of a soft cushion pad that can be easily cut. This is

prohibited hindsight reconstruction. Without the teaching of the Applicant's invention, no reasonable person or no person of skill in the art would ever consider a hard leather cuff as the equivalent or as the same as the Applicant's soft cushion pad which is easily cut or torn.

Regarding Claim 3 the Examiner concludes that Ogburn teaches "right and left means for readily attaching and detaching whereby said right and left arm sections may be easily and readily attached and detached from said central portion of said at least one member." The Ogburn cuffs, when unattached, are flat rectangular pieces of hard stiff leather, which may be rolled over and strapped, using strap (21), to the central strap (11) in order to secure the arms and legs of a patient inside the now rolled cuffs (16 and 17). However, there is no indication in the Ogburn patent the Applicant was able to discover that there is <u>any</u> means for removing the cuffs (16 and 17) from the central strap (11) as the Examiner implies. Ogburn does disclose that the cuffs (16 and 17) have slits (32) for slidable adjustment on the strap (11). Applicant concedes that the Ogburn cuffs (16 and 17) may be wrapped around a patient's wrist, thereby securing a patient's arms to the central strap (11). However, Applicant traverses the apparent conclusion of the Examiner that Ogburn teaches a right and left arm section, which may be easily and readily attached and detached from a central portion of a soft cushion pad.

#### The Examiner notes that Ogburn fails to teach:

"the at least one member being a soft cushion pad;

the right and left arm sections comprising upper and lower sections foldable around upper and lower parts of a patient's right and left arms;

the at least one soft cushion pad being radiolucent;

the at least one soft cushion pad comprising first and second rectangular sections connected together, thereby forming a generally H-shaped pad with right arm upper section, left arm upper section, right arm lower section, and left arm lower section comprising legs of the H; and

wherein the H-shaped pad has a width approximately equal to the length of a patient's torso."

In order to remedy these acknowledged deficiencies of Ogburn, the Examiner reasons that Witter '225 shows a patient hold and turn device comprising a soft radiolucent cushion pad (20) positionable under a patient's body. (Column 1, lines 59-63; Column 2, lines 34-36). Consequently, Witter prior art is apparently offered to show a "soft radiolucent cushion pad positionable under a patient's body.' Witter actually discloses a sheet (10) with a width several times it length. The width of the sheet (10) is constrained to be greater than the width of the mattress (11) of which the device will be used, so the sheet may be wrapped substantially around a bed patient without discomfort to the patient. (Witter, Column 1, lines 60-67). It describes a fleece cushion (20) apparently mounted on the sheet (10) between the opposite side edges (14 and 19). (Witter, Column 2, lines 7-10). Applicant concedes that there are pillows, mattress pads, and the like which could be reasonably described as a soft cushion pad and which are positionable under a patient. However, there is nothing in the Witter reference that suggests that the Witter sheet and fleece pad are radiolucent or suggest any reason why they should be.

The Examiner then reasons that Tari '366 shows an arm support (10) for a patient's arm comprising separate upper and lower assemblies (30 and 32) positionable about the upper and lower sections (18 and 22) of an arm of a patient (14), the upper and lower assemblies configure to immobilize the entire arm of a patient (Column 3, lines 62-67), wherein each of the upper and lower sections includes a means for attaching (45 and 46). Applicant concedes that Tari '366 discloses a means for immobilizing one arm of a patient to facilitate imaging of the patient by radiographic or other means during an angioplasty procedure. This is explained in the Tari application. The purpose is to immobilize a single arm to facilitate radiographic imaging so that the arm described as "relatively opaque" (Tari, Column 2, lines 50-51) does not interfere with a radiographic image of a patient's heart.

Using the Tari and Witter references, the Examiner then "cherry picks" items from each reference, taking these cherry picked items both out of context and out of their field of use, then claims that, when combined with Ogburn, they render the Applicant's invention obvious. The Examiner first states that Witter teaches a "soft cushion pad" and uses it to turn the hard leather cuffs (16 and 17) of Ogburn into the "soft cushion pad" allegedly taught by Witter. The

Examiner then takes the Tari single arm positioning device and says it would be obvious to use it to modify Ogburn to provide a left and right arm upper and lower sections to provide support for the patient's left and right arms respectively. Even with the "cherry picking" done by the Examiner, the combination is still deficient and does not render the Applicant's Claims 1, 2, and 3 obvious. The cumulation of Ogburn, Witter, and Tari is deficient in the following specific ways. The Applicant's invention is not simply for positioning a patient's body, but is designed to "provide a cushioning effect for the patient's arm while securing them in place in a position which will not threaten a stretching injury to any nerves within the patient's arm. The arm protector pad (10) will shield the patient's arm from pressure that may come from a physician or other operating room personnel positioned around the operating room table (50) to the respective portions of the patient's arm covered by the arm protector pad (10)." (Application Page 8, line 23 to Page 9, line 4). The Applicant's disclosure also describes how the arm protector pad could be used to secure a patient's arm against a patient's sides and to provide cushioning protection of the patient's arm against pressure caused by straps or other devices when a patient is in transit in an ambulance. (Application Page 11, lines 12-23). Consequently, the Examiner must use the hard leather cuffs (16 and 17) of Ogburn, use the fleece pad of Witter, and use the upper and lower straps of Tari, to extend the leather cuffs of Ogburn to Tari's upper and lower sections for a patient's arm, then take the fleece pad of Witter and extend it out to replace the leather cuffs with the cushion pad of Witter in order to provide the arm protection pad of the Applicant's invention. Neither Ogburn, nor Tari, nor Witter discuss or explain the problem solved by the Applicant's invention of injuries to the patient's arm from outside forces, such as straps on a stretcher or pressure from operating room personnel. It is only because of the recognition and solution of the problem offered by the Applicant's invention that the Examiner is motivated to make the combination she makes to claim that these disparate pieces of prior art render the Applicant's Claim 1 obvious.

The Examiner offers no explanation as to why the addition of Tari and Witter remedy the deficiencies of Ogburn as a reference for Claims 2 and 3 of the Applicant's invention. The Applicant will not repeat the arguments made above regarding the deficiencies of Ogburn for Claims 2 and 3, since the Examiner offers no explanation of why Witter and Tari remedy these deficiencies of the Ogburn reference.

With regard to Claim 4, the Examiner states: "Ogburn broadly addresses the type of material suitable for the arm protection pads. (Column 2, line 4), it would have been obvious to one of having ordinary skill in the art at the time the invention was made to make them radiolucent." The Examiner reasons the motivation would have been provided by the need to permit radiological operations to be performed on a patient while positioned in the arm protection apparatus. First, Ogburn does not disclose or discuss any arm protection apparatus, but rather cuffs for restraining a patient's arms or legs. There is no discussion in Ogburn of any desirability or need for such a restrained patient to undergo x-ray procedures. Moreover, it is clear that because the cuffs (16 and 17) slide on the central strap (11), one could reposition the cuffs to remove a patient's arms from a position where they might interfere with x-ray procedures. In short, it is only because the Applicant's device, which is used in actual operations where it is common in the course of the operation to take x-rays to determine the progress of the operation or to determine the placement of medical devices and the like, would teach a need for radiolucent materials. The Ogburn invention for restraining an insane or delirious patient does nothing to suggest the need for radiolucent material and it is only because of the teaching of the Applicant's invention that the Examiner would see a need to make the hard leather cuffs (16 and 17) of Ogburn radiolucent.

Regarding Claims 5 and 6, the Examiner scarcely bothers to offer a reason why Ogburn, Witter, and Tari in combination disclose a "generally H-shaped pad having a width approximately equal to the length of the patient's torso." None of these devices disclose such shapes or dimensions. The specific use of the Applicant's device during operative procedures where there is a need to position and cushion a patient's arm throughout the procedure and to make Applicant's invention easily repositioned for x-rays or to place intravenous lines and the like are all facilitated by the general shape and size of the Applicant's invention. None of these needs met by the Applicant's invention are "inherent" in the Ogburn, Witter, or Tari inventions. Again, the Examiner, unable to actually offer a basis for holding the Applicant's invention obvious, simply asserts without any factual basis that these features of the Applicant's claims in Claims 5 and 6 are "inherent" in the prior art.

Claims 7-11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ogburn '293, in view of Witter '225. The Applicant will note that the Examiner's arguments regarding Claims 7-11 largely repeat the same arguments regarding Claims 1-6 and repeat the same mistakes, false assumptions, and fabrications. Again, the Examiner starts by saying Ogburn shows an "arm protection apparatus." The Applicant again traverses that conclusion of the Examiner and incorporates by reference herein the arguments made above regarding Claim 1. The Examiner again concludes there is "at least one arm section cushion pad (19)." The Applicant again traverses the conclusion of the Examiner and incorporates by reference herein the arguments made to this same conclusion of the Examiner for Claim 1. As noted above, the Ogburn invention discloses hard leather cuffs to fit around the ankles or wrist of a patient. It is not a cushioning pad. There is cushioning (19) positioned within the hard leather outer covering cuffs (16 and 17). The cushion within this hard leather cuff no more makes a leather cuff a cushion pad than the soft seats in a 747 airplane make the 747 airplane a soft cushion pad. Again, the combination of Ogburn and Witter together do not suggest the need of providing a cushion for a patient's arm against an outside force, such as operating room personnel or a securing strap on a stretcher.

Regarding Claim 8, the Examiner states that apparently Ogburn provides a central member sized whereby there is a plurality of arm sections. In fact, Ogburn teaches two hard leather cuffs (16 and 17) slidably mounted on a central strap (11). There is no teaching of a soft cushion pad arm section, either singularly or as a plurality.

Regarding Claim 10, the Examiner concludes Ogburn discloses means for readily attaching and detaching a plurality of arm sections to secure a patient's arms. Ogburn does disclose means for adjusting the size of the cuffs to fit different sized wrists using a variety of strap arrangements. These strap arrangements are threaded through buckles and are designed not for ready attachment or detachment, but rather to securely restrain an insane or delirious patient's arms or legs. Consequently, the basic premise of the Ogburn patent to restrain a patient's arms teaches away from cuffs that are readily attached and detached. If the Ogburn hard leather cuffs (16 and 17) are readily attached and detached, the patient would be readily able to remove his arms from these cuffs defeating the restraint purpose basic to the Ogburn patent.

Regarding Claim 11, the Examiner concludes, apparently regarding the Ogburn patent, that they are "constructed of material that is easily cut." The Ogburn patent, in fact, disclose hard leather cuffs, which are designed to secure an insane or delirious patient. As argued above, the basic premise of the Ogburn patent of restraining an insane or delirious patient argues against leather cuffs that can be easily cut since it would defeat the basic purpose of the Ogburn patent of patient restraint.

Regarding Claim 12, the Examiner reasons that there are "two arm sections and each arm section is sized to fit around approximately one-half of a patient's arm." Ogburn teaches cuffs which are sized to fit around a patient's wrist and are so illustrated in the Ogburn figures. At most, Ogburn teaches two patient cuffs for the left and right arms or legs of a patient. The Examiner does nothing to explain how the left and right cuffs of the patient multiply themselves by a factor of two and change their orientation and size to cover a patient's arm. Consequently, the Applicant traverses the conclusion of the Examiner regarding the teaching of the Ogburn patent for Claim 12.

The Examiner adds the Witter fleece pad (20) to remedy the deficiencies of the Ogburn patent, claiming it would have been obvious to add a cushion pad of Witter to the Ogburn invention to "enhance the comfort of a patient." Had the Applicant's invention stopped with a soft cushion pad only underneath a patient, the Examiner's point might be well-taken. However, the Applicant's invention is not designed to enhance the comfort of a patient. After all, a patient on an operating table is already lying on some kind of foam pad. Rather it is designed to position and to protect the arms of a patient from outside pressure during operations. As this was explained above regarding Claim 1, that explanation is incorporated by reference herein and will not be repeated. However, combining the Witter reference with Ogburn does not teach soft cushion pads around a patient's arms to protect the patient's arm from outside pressure. Without the teaching of this application, there would be no reason to consider combining Witter with Ogburn, which is prohibited hindsight reconstruction.

Regarding Claim 9, the Examiner again concludes that it would be obvious to make the

invention radiolucent without referencing anything in the Ogburn or Witter patents that teaches the desirability of radiolucent arm cushion pads. The Applicant will not repeat the arguments made in response to the examiner's rejection of Claim 4, but will incorporate them by reference herein.

Claim 12 was rejected as unpatentable over the combination of Ogburn in view of Witter and further in view of Tari. The Examiner reasons that Tari adds an upper arm support and a lower arm support. In fact, Tari does teach support for the upper and lower sections of a patient's arm. However, he only shows it for one arm. Applicant traverses the conclusion of the Examiner that Tari teaches four arm sections. However, neither Witter, Ogburn, nor Tari teach four arm cushion pads each sized to fit around approximately one-half of a patient's arm. Consequently, these references, neither combined nor singularly, render obvious Claim 12.

# 112 - Paragraph 2 Rejections

Applicant must note, before meeting the substance of the 112 paragraph 2 rejection, the timing and the origin of these rejections. Applicant's original claims had the objected to language. The first Office Action entered by the Examiner did not raise a 112 indefiniteness rejection. Applicant amended claims in response to the first Office Action. These amended claims again had the objected to "indefinite" terms. However, the final Office Action did not raise an indefiniteness rejection as to these terms. The Examiner then indicated that Claims 1-6 would be allowable, if amended, in a phone call to the Applicant on February 9, 2005. The Examiner suggested allowable claims which used the terms the Examiner later claimed were indefinite. The patent process is rigorous and difficult enough without an Applicant being required to meet a "moving target" where, when one set of objections or rejections are overcome, an entirely new and different set are raised, which could have, and should have been raised in an initial earlier Office Action.

It is not now, nor has it ever been, the law in patent claims that operational definitions must be provided for terms in a patent claim. In this regard, it is worth noting that the prior art Ogburn '293 patent in Claim 1 uses the term "flexible" fabric. Relative terms like "flexible", which are not defined within the claim, are commonly found in patent claims, where ordinarily to define these terms reference is made to either the disclosure in the patent or the common understanding of those

terms. Here, in the Ogburn patent, the term "flexible" could have just as easily been rejected in this application as the Examiner rejected the term "easily" in the Applicant's claims. The Ogburn fabric is flexible compared to what - a sheet of armor plating or a sheet of tissue paper?

In interpreting and understanding the terms in a patent claim, the ordinary and customary meaning of a claimed term is the meaning the term would have to a person of ordinary skill in the art in question at the time of the invention - that is, of the effective filing date of the patent application. Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Circ. 2005) (en banc). In the Phillips case, a person of ordinary skill in the art is deemed to have read the claim term not only in the context of the particular claim in which the disputed term appears, but also in context of the entire patent, including the specification. With these standards in mind, consider the disputed terms in the Applicant's claims and whether they are sufficiently defined either by their common and ordinary use or by the specification making reference to those terms.

The Examiner rejected these term "easily" in Claim 2 as a relative term which renders a claim indefinite, asserting that one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Here, the Applicant's invention is a surgical arm positioning pad. One of ordinary skill in the art, who would be required to use the invention, is obviously operating room personnel such as an anesthesiologist, surgeon, or operating room nurse. It would be to their knowledge and understanding that the invention is addressed. The specification discusses the current state of the art, including the use of a rigid device called a "sled or toboggan" (Application, page 2, line 4). The Applicant discusses the drawbacks of this invention, including the fact that this "protective device makes it difficult to check IV and arterial line sites" during a procedure. (Application, page 2, lines 12-13). In the Summary of the Invention, the Applicant explains that the invention should be "easily cut or torn by standard cutting devices such as scissors." (Page 3, lines 19-20.) The purpose of constructing such material is to allow portions of the device to be remove to provide visualization of a portion of the patient's body, which might otherwise be concealed under some portion of the invention. The inventor goes on the explain that, when necessary, a portion of the arm protector pad may be cut away or folded to expose a particular portion of the patient's hand or arm (page 4, lines 18-19). In the Detailed Description of the Drawings, the Applicant goes

further to explain and to define requirements of Claim 2. In explaining that the foam material that forms the arm protector pad (10) is soft and that "if necessary, the foam material can be cut away with standard cutting tools available in an operating room, such as scissors." (Application, page 9, lines 8-9). Moreover, the claim itself requires not only that the material be cut, but that it be "easily" cut. "Easily", as a dictionary definition usually is "causing or involving little difficulty; requiring or indicating little effort." Consequently, the operative definition provided by the Applicant's specification for the objected to term "easily" in Claim 2 is that the soft cushion pad be made of material that involves little difficulty or little effort to cut using cutting instruments that are readily and ordinarily available in an operating room. Applicant goes on to define a specific preferred embodiment that the arm protector pad foam material "could be constructed with preperforated tear-a-way sections as is necessary or appropriate to facilitate removal of a portion of the arm protector pad as may be necessary to gain access to a vein or artery of a patient. (Application, page 9, lines 10-12).

Consequently, the Applicant's respectfully suggests that here the "easily cut" material required by Claim 2 of the Applicant's invention, is definite and understood by a person of ordinary skill in the art - that is, a surgeon, anesthesiologist, or operating room nurse. These people of ordinary skill in the art are familiar with and use the cutting tools that are readily available in an operating room as a matter of course in the practice of their profession and would have no difficulty understanding what kind of material would be required to enable operating personnel using those same tools to, without undo effort, to cut away or remove a portion of the materials forming the arm protector pad. The Applicant again notes that through two Office Actions and a phone call the Examiner had no difficulty understanding these terms and suggests that the Examiner's original understanding is more accurate and in keeping with the requirements for patent claiming and for claim interpretation as established by the case law than the indefiniteness objection imposed by the Examiner in the Examiner's later Office Actions.

Claims 3 and 10 were objected to. Claim 3 was objected to because of the term "easily and quickly" used in Claim 3 or because of the term "quickly" used in Claim 10. In both Claims 3 and 10, the language reference is "means for" claim language. The "means for" language is

authorized by §112(6). To determined the meaning of the "means for" language, reference is made to the specification. In Re Donaldson Co., Inc., 60 F.3d 1189, 29 U.S.P.Q. 2d 1945 (1994). Here, the specification specifically describes that there are attachment tapes (Specification, page 9, lines 17-18). It describes one embodiment of the attachment tapes as a "hook-and-eye attachment tape" (Velcro<sup>™</sup>-like) (specification, page 4, lines 12-13). Consequently, the means for attaching, which quickly and easily attach and detach, are defined by the "means for" language to be what is disclosed in the specification and the equivalents, hence it would be Velcro<sup>™</sup>-like hook-and-eye attachment tapes or their equivalents. Consequently, the terms "easily and quickly" simply are descriptive ones that describe the ordinary and known qualities of a Velcro™-like or equivalent hook-and-eye attachment means. Consequently, the Applicant simply traverses the Examiner that these terms in any way render a "means for' claim indefinite, when there is support for use of the "means for" claim language in a specification, as there clearly is here.

# **CONCLUSION**

The Applicant has fully answered all objections and rejections of the Examiner to Claims 1-12. Consequently, it is believed these claims are in a condition for allowance and the same is respectfully requested from the Board of Patent Appeals.

This the  $\frac{3}{3}$  day of  $\frac{1}{3}$ , 2006.

Respectfully Submitted,

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#### **CLAIMS APPENDIX**

- 1. An arm protection apparatus for positioning a patient's arms when in a prone or supine position on a patient support comprising:
  - at least one soft cushion pad with a central portion positionable under the patient's body;
  - (b) on said at least one soft cushion pad, a soft cushion pad right arm upper section positionable around an upper right arm of a patient including means for attaching said soft cushion pad right arm upper section to said central portion of said at least one soft cushion pad so that said soft cushion pad right arm upper section is folded around a patient's upper right arm;
  - (c) on said at least one soft cushion pad, a left soft cushion pad arm upper section positionable around an upper left arm of a patient including means for attaching said left arm soft cushion pad upper section to said central portion of said at least one soft cushion pad so that said soft cushion pad left arm upper section is folded around a patient's upper left arm;
  - (d) on said at least one soft cushion pad, a right soft cushion pad arm lower section positionable around a lower right arm of a patient including means for attaching said soft cushion pad right arm lower section to said central portion of said at least one soft cushion pad so that said soft cushion pad right arm lower section is folded around a patient's lower right arm;
  - (e) on said at least one soft cushion pad, a soft cushion pad left arm lower section positionable around a lower left arm of a patient including means for attaching said soft cushion pad left arm lower section to said central portion of said at least one soft cushion pad so that said soft cushion pad left arm lower section is folded around a patient's lower left arm.
- 2. An arm protection apparatus for positioning a patient's arms when in a prone or supine position on a patient support of Claim 1 wherein said soft cushion pad is made of material that is easily cut whereby a portion of the soft cushion pad may be cut away when necessary for

visualizing a portion of a patient's body that may be otherwise covered by said at least one soft cushion pad.

- 3. An arm protection apparatus for positioning a patient's arms when in a prone or supine position on a patient support of Claim 2 wherein said soft cushion pad right upper arm section means for attaching, said soft cushion pad left arm upper section means for attaching, said soft cushion pad right arm lower section means for attaching readily attach and detach whereby said soft cushion pad right arm upper section, soft cushion pad left arm upper section, soft cushion pad left arm lower section, and soft cushion pad left arm lower section may be easily and quickly attached and detached from said central portion of said at least one soft cushion pad.
- 4. An arm protection apparatus for positioning a patient's arms when in a prone or supine position on a patient support of Claim 3 wherein said at least one soft cushion pad is radiolucent.
- 5. An arm protection apparatus for positioning a patient's arms when in a prone or supine position on a patient support of Claim 4 wherein said at least one soft cushion pad is comprised of a first rectangular section, a second rectangular section, with said first and second rectangular sections connected thereby forming a generally H shape with said soft cushion pad right arm upper section, soft cushion pad left arm upper section, soft cushion pad right arm lower section, and soft cushion pad left arm lower section comprising legs of said general H shape.
- 6. An arm protection apparatus for positioning a patient's arms when in a prone or supine position on a patient support of Claim 5 wherein said generally H shape has a width approximately equal to the length of a patient's torso.
- 7. An arm protection apparatus for positioning at least one arm of a patient comprising:
  - (a) at least one central cushion pad, said central cushion pad sized to be positioned under the torso of a patient;
  - (b) attached on said central cushion pad, at least one arm section cushion pad with an

- arm end extending away from said central cushion pad, said at least one arm section cushion pad sized to loop around at least a portion of an arm of a patient;
- (c) means for attaching said arm end of said at least one arm section cushion pad to said central cushion pad whereby at least a portion of an arm of a patient may be contained within said at least one arm section cushion pad looped around an arm of a patient and held into place in proximity to a patient's torso.
- 8. An arm protection apparatus for positioning at least one arm of a patient of Claim 7 wherein said central cushion pad is sized whereby there are a plurality of said arm section cushion pads.
- 9. An arm protection apparatus for positioning at least one arm of a patient of Claim 8 wherein said plurality of arm section cushion pads are radiolucent.
- 10. An arm protection apparatus for positioning at least one arm of a patient of Claim 9 wherein said means for attaching readily attach and detach whereby said plurality of arm section cushion pads may be quickly used to secure a patient's arm or to unsecure a patient's arm in proximity to a patient's torso.
- 11. An arm protection apparatus for positioning at least one arm of a patient of Claim 10 wherein said plurality of arm sections cushion pads are constructed of material that is easily cut whereby a portion of said plurality of arm section cushion pads may be cut away when necessary for visualizing a patient's arm folded within said arm section cushion pads.
- 12. An arm protection apparatus for positioning at least one arm of a patient of Claim 11 wherein there are four arm section cushion pads attached to said central cushion pad, each arm section cushion pads sized to fit around approximately one-half of a patient's arm.

## **CERTIFICATE OF SERVICE**

I, Michael E. Mauney, do hereby certify that a copy of the foregoing Appeal Brief in:

In Re Application of: Frank Forrest Humbles

Serial No.:

10/698,205

Filing Date:

31 October 2003

Invention:

SURGICAL ARM POSITIONING PAD

has this day been duly served upon:

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This the <u>3</u> day of <u>May</u>, 2006.

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